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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,616	11/15/2005	Roy Curtiss III	56029-51044	4042

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
09/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDOCKET@THOMPSONCOBURN.COM

Office Action Summary	Application No.	Applicant(s)	
	10/511,616	CURTISS, ROY	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17,19 and 21-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

The restriction on 4/8/2008 has been vacated.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-10, 12-16, 19, 21-26, and 32-40 drawn to a live attenuated derivative of a pathogenic Salmonella species consisting essentially of (a) a means for regulatable expression of a gene that encodes a regulatory protein, wherein non-expression of said regulatory protein in vivo causes synthesis of a first antigen that is conserved among Salmonella species and E. coil strains; and (b) a means for regulatable synthesis of a first carbohydrate antigen, wherein said first carbohydrate antigen ceases to be synthesized in vivo, exposing a second carbohydrate antigen that is conserved among Salmonella species and E. coil strains; wherein said attenuated derivative has enhanced ability to induce cross-protective immunity against Salmonella species and E. coil strains, a live attenuated derivative of a pathogenic Salmonella species, and vaccine.
2. Group II: claims 11 and 17, drawn to a method for inducing an immune response sufficient for protection against infection by Salmonella species and E. coil strains and a method of inducing a cross-protective immune response against Salmonella species.
3. Group III: claims 27-31, drawn to a recombinant bacterial strain consisting essentially of a means of regulatable expression of a virulence gene.
4. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group 1 is The special technical feature of Group I is a live attenuated derivative of a pathogenic Salmonella species consisting essentially of (a) a means for regulatable expression of a gene that encodes a regulatory protein, wherein non-expression of said regulatory protein in rive causes synthesis of a first antigen that is conserved among Salmonella species and E. coil strains; and (b) a means for regulatable synthesis of a first carbohydrate antigen, wherein said first carbohydrate antigen ceases to be synthesized in vivo, exposing a second carbohydrate antigen that is conserved among Salmonella species and E. coil strains. The technical feature is unpatentable over Roy et al WO 2001/83785A2 Date November 8, 2001 in view of Roy et al US Patent 6,024,961 Date February 15, 2000. Roy et al WO 2001/83785A2 teach a live attenuated derivative of a pathogenic Salmonella species consisting essentially of (a) a means for regulatable expression of a gene that encodes a regulatory protein, wherein non-expression of said regulatory protein in rive causes synthesis of a first antigen that is conserved among Salmonella species and E. coil strains; and (b) a means for regulatable synthesis of an glycoprotein and polysaccharides which act as antigens, wherein glycoprotein and polysaccharides which act antigens ceases to be synthesized in vivo, exposing an antigen that is conserved among Salmonella species and E. coil strains.

Roy et al WO 2001/83785A2 does not teach carbohydrate antigens in step (b) of a live attenuated derivative. However of Roy et al US Patent 6,024,961 teaches a live attenuated derivative of pathogenic Salmonella species such as LPS O-antigen.

It would have been prima facie obvious at the time the invention was made to incorporate carbohydrate antigens as taught by Roy et al US Patent 6,024,961 into the method as taught by Roy et al WO 2001/83785A2 because both teach live attenuated derivative of a pathogenic Salmonella species used in a vaccine for delivery of antigens.
5. Group II is a method of use of the technical feature in Group I, a live attenuated derivative of a pathogenic Salmonella species consisting essentially of (a) a means for

regulatable expression of a gene that encodes a regulatory protein, wherein non-expression of said regulatory protein in rive causes synthesis of a first antigen that is conserved among Salmonella species and E. coil strains; and (b) a means for regulatable synthesis of a first carbohydrate antigen, wherein said first carbohydrate antigen ceases to be synthesized in vivo, exposing a second carbohydrate antigen that is conserved among Salmonella species and E. coil strains.

6. The technical feature of Group III is a recombinant bacterial strain consisting essentially of a means of regulatable expression of a virulence gene.

The technical feature of Group I, a live attenuated derivative is known in the art. Group I lacks unity with Groups II-III, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. Applicant is required to elect a combination from each species from Species A and Species B from Group I or a single individual from Species A from Group II.

Species Group I

a) Species A-regulatory protein;

Species 1-fur;

Species 2-rpoS;

Species 3-phoPQ;

Species 4-dam;

Species 5-ompR;

Species 6-cya;

Species 7-crp;

b) Species B-mutation;

Species 1-Δ(gmd-fcl)-26;

Species 2-ΔagfBAC811;

Species 3-ΔbcsABZC2118;

Species 4-ΔbcsABZC 2119;

Species 5-ΔadrA1418;

Species 6-ΔmlrA34;

Species 7-ΔyhiR36::TT;

Species 8-ΔendA2311;

Species 9-ΔrelA1123;

Species Group II

a) Species A-regulatory protein;

Species 1-aroA;

Species 2-aroC;

Species 3-aroD;

Species 4-cdt;

Species 5-ompF;

Species 6-cya;

Species 7-crp;

Species 8-ompR;

Species 9-htrA;

Species 10-hemA;

Species 11-purA;

Species 12-purB;

Species 13-rfa;
Species 14-rfb;
Species 15-asd;
Species 16-ompC

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Shanon Foley can be reached on 571-272-0898 and Robert Mondesi on

571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nina A Archie/
Examiner, Art Unit 1645
/N. A. A./
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/Mark Navarro/
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